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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/077, 194 12/04/98 BOHN

M 02481.1596

EXAMINER

HM12/1024  
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WASHINGTON DC 20005-3315

KIM, V

ART-UNIT	PAPER NUMBER
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1614

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**RECEIVED**

OCT 31 2001

FINNEGAN, HENDERSON,  
FARABOW, GARRETT & DUNNER, LLP.

Docketed 10/31/01 CPE/AR/b25  
Case 5077-1596  
Due Date 11/24/02 11/25/02  
Action Reusable Due  
By

JMS 10-3-01

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/077,194	BOHN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Vickie Kim	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 38-42,48 and 49 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 38-42,48 and 49 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>24,26</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Status of Application***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2001 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 the form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 38, 40, 42 are rejected under 35 U.S.C. 102(a) as being anticipated Dascalu (WO 96/29045).

Dascalu teaches the treatment of dandruff, seborrheic dermatitis, using an effective amount of composition comprising ciclopirox olamine (ciclopirox) as an active agent; see claim 4. The patented composition of ciclopirox olamine is encompassed by the formula required by the instant claims; see claim 4.

3. Claims 38, 40-42 and 48-49 are rejected under 35 U.S.C. 102(a) as being anticipated Lange (US 5,132,107) or Thorel(FR 2694694).

Lange teaches an anti-seborrheic composition comprising an effective amount of piroctone olamine and its utility as anti-dandruff shampoo. It also teaches pH levels of the composition ranging from 3 to 6; see claims 7 and 15, especially column 5, lines 64-65. Thorel teaches 1-hydroxy-2(1h)-pyridone derivatives such as piroctone olamine(octopirox) as an effective active agent for treating seborrheic dermatitis; see abstract and column 9, lines 29.

4. Claims 38, 40-42 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Saint-Leger(US 5,650,145).

Saint-Leger teaches 1-hydroxy-2(1h)-pyridone derivatives such as Ciclopirox or Octopirox as an effective active agent for treating seborrheic dermatitis; see column 2, lines 29-32 and column 5, lines 45 thru column 6, lines 40. The tested compositions (example 1-6) stabilize and/or reduce seborrhea. The surfactants required by claim 48 is taught at column 3, lines 41-43.

All the critical elements are anticipated by the cited references. Thus all the claimed subject matter is not patentably distinct over the prior art of the record. It is noted that the cited reference meets the claims requirement. The therapeutic effects of 1-hydroxy-2(1h)-pyridone alone is also well documented and evidenced by Rivalland(1994) in case of that applicant may question about.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dittmar(US 4,185,106) in view of Descalu and Saint-Leger.

Dittmar teaches 1-hydroxy-2-pyridone derivatives such as Ciclopirox(column 2, line 57), Octopirox(column 2, line 47), and the other species required by the claim 39(column 2-4). It also teaches its utility as an anti-dandruff agent where it has anti-mycotic activity against dandruff causing fungi.

Applicant's claim differs because it requires the specific bi-cyclic substituents in R<sub>4</sub> position and it requires the term "seborrheic dermatitis" rather than dandruff.

However, Descalu teaches Dandruff is, in fact, seborrheic dermatitis of the scalp. It also support Dittmar's reference by teaching that 1-hydroxy-2 pyridone derivative (e.g.Ciclopirox) is effective antifungal agent used in the treatment of dandruff; see column 3, line 12. Saint-Leger also teaches the treatment of seborrhea and anti-seborrheic effects of 1-hydroxy-2-pyridone derivatives set forth in 102 rejection.

Therefore it would have been obvious to one of ordinary skill in the art to make such modifications(formulating various derivatives) as taught by Dittmar, to apply to treat seborrheic dermatitis(e.g. dandruff). One would have been motivated to do so within the skilled level of one having ordinary skill in the art, so that one would increase it's efficacy(see Dittmar;column 7, lines 50-55) and the selection option for the

treatment. Furthermore, one would have been motivated to use such modification alone or in combination with other active anti-seborrheic agent to have additive or other benefits taught by all these cited references. In response to the applicant's argument(see paper no.8) that alleges 1-hydroxy-2-pyridones can not be an antiseborrheic agent because Dittmar teaches anti-seborrheic agent as an active additive. However this allegation has now been clearly answered where the anti-seborrheic agent in Dittmar's reference(column 6, line 24) is secondary anti-seborrheic agent which has been added to enhance its benefit.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

***Conclusion***

All the pending claims are rejected.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,  
Patent examiner  
October 16, 2001



William Jarvis  
Primary examiner  
Art unit 1614